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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/675,161

09/30/2003

Eric Joel Benjamin

AM101003

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05/13/2009

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PATENT LAW GROUP
5 GIRALDA FARMS
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EXAMINER

SIMMONS, CHRIS E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/675,161	Applicant(s) BENJAMIN ET AL.	
	Examiner CHRIS E. SIMMONS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 04 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 35-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 12/04/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 1-17 and 35-38 were rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0144252.

This rejection is maintained.

Applicant argues that the reference does not say anything regarding stability or the need to stabilize. In response to applicant's argument that "stability" is not mentioned in the reference, stability does not have to be the motivation recognized in the prior art to render the claimed invention obvious. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant further asserts that the reference does not provide direction relating to useful amounts of excipients. The examiner does not agree and contends that the reference discloses a range of about 5% to about 98% of excipient are useful for the invention. Furthermore, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *MPEP* § 2144.05. In this case, the amount of excipient disclosed in the reference overlaps the claimed amounts.

Applicant argues that the reference does not teach or suggest the selection of calcium carbonate as the excipient or in an amount that is sufficient to achieve pH 8 or greater. A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. Obviousness only requires a reasonable expectation of success. The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *MPEP* § 2143.02. In the instant case, EKB-569 and calcium carbonate are both disclosed in the reference as acting as the EGFR TKI and the excipient, respectively. The amount of picking and choosing is minimal considering the fact that only 6 EGFR TKI are to be selected (see paragraph 0025 of the prior art) and only 3 diluents, 2 of which are basic (see paragraph 0035.

Applicant's arguments that the reference teaches away from using EKB-569 because ZD 1839 is preferred as the EGFR TKI are not found to be persuasive because disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *MPEP* § 2123[R5].

Applicant asserts that the since the reference recites "amount of excipients", one skilled in the art is not taught the use of a single excipient in an amount of 5% or more. This assertion is not persuasive because the reference discloses at paragraph [0031] that one excipient may be used in the composition comprising the EGFR TKI.

Applicant also asserts that the examiner cited teachings in the instant specification to support the proposition that a skilled chemist would find the claimed invention obvious. The examiner only referred to the instant disclosure to show that the pH of the suggested compositions would necessarily possess the claimed pH range since the specification teaches that 5% calcium carbonate renders a composition with a pH of 9.24. The specification was simply used to show that even a minimal amount of the basic excipient is sufficient render the claimed pH. Furthermore, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be a naturally present. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *MPEP* § 2112.01 I. In this

case, the suggested chemical composition is the same as what is claimed, therefore, the pH would necessarily be the same, especially since it is disclosed in the instant specification that a minimal amount of basic excipient is sufficient to achieve the claimed pH.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, the judgment on obviousness only took into account knowledge disclosed in the reference and knowledge that was within the level of ordinary skill at the time of the invention and was not gleaned only from the instant specification.

There is nothing in the instant claims that would preclude the inclusion of another active agent in the composition, as such, applicant's argument that another active agent is present in the reference is not found to be persuasive.

Applicant implies that increased stability is unexpected. For example, applicant's Figure 1 shows that EKB-569 degradation in slurries containing basic excipients was more pronounced in the acidic region and most stable at pH values of 8 and higher. The examiner does not agree that these results are unexpected, however, given that EP 0

Art Unit: 1612

475 482 B1 (previously cited by applicant) teaches stabilizing acid addition salts of poorly soluble drugs by adding basic excipients.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is

Art Unit: 1612

(571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612